

Application no 10/642,813

Application Dated August 19, 2005

Reply to office action of April 24, 2006

**Amendments to the Drawings:**

The attached sheets of drawings includes changes to Fig 1 and 2 and they replace original Fig 1 and 2. A fig 3.A is added to showing large radius circular coil and fluoroscopic

It shows small generator in Pacemaker or Implantable Defibrillator (PPM/ICD)

3 small cylindrical magnets

4 circular cylindrical coils encircling the magnet

5 Box (can) of PPM/ICD

**Fig 2**

It shows an insulated needle and radiologically distinct pole

6 needles

7 insulation with thick distal edge

8 skin

9 PVC like material

10 outer surface of PPM/ICD

11 gel-like insulation

12 radiologically distinct pole

**Fig 3.A**

It shows large radius circular coil and fluoroscopic facility from an angulated view.

13 U arm cath lab with fluoroscopic facility

14 large radius circular coil

**Attachment:** Replacement sheet

Annotated sheet showing changes

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Application Dated August 19, 2003  
Reply to office action of April 24, 2006

#### REMARKS/ENCLOSURES

##### *Priority*

In response to examiner's objection to priority  
Application no 60/406,987 dated 30<sup>th</sup> August 2002.  
It mentions two distinct radiological poles (part A, para2), magnet is encircled by a coil (part A, para1), poles covered by an insulation (part A, para2), telemetry wand (hardware input, part B), compatibility with an internet /network connection facility (remote programming, part B).

##### *Drawings*

New drawings are enclosed  
Fig 3 showing the large circle coil is added.

##### *Note*

I had not submitted it earlier as such fluoroscopic facilities(U or C arm cath labs using x-ray) are commercially available and being used in cardiac cath labs for many years, they are used in pacemakers especially biventricular pacemaker and more so during coronary angiography and angioplasty. I am using this since 1985 and I am sure that they were available earlier also.

I will try to explain you the need for this in following few words

When I tested this concept a crude mechanism was made in which there was a large radius circular coil, and it was encircling a small generator with cylindrical magnet surrounded by a cylindrical coil. The large radius circular coil tended to move the generator and it will work only if the magnet of generator was in centre of it and perpendicular to it. The PPM/ICD box will be inside the human body so I thought of adding the radiological marker to the box of PPM/ICD to help this desired alignment.

##### *Claim objections*

Page 4&5 Para 4-10

Claim objection is moot in view of cancellation of claim 1-16. In new claims I have incorporated the recommended changes to the best of my capacity. If any other shape is found highly objectionable by you in claims mentioning shape please delete this phrase. I have only tested a cylindrical magnet.

##### *Claim rejections 35 USC 112*

Page 5 Para 12

I have corrected it within my understanding of USPTO guidelines

Page 5 Para 13

I have corrected it to the best of my ability and incorporated your suggestions. Fluoroscopy facility means the U or C arm cath labs which are available for many years as described above which we the interventional cardiologists use for various cardiac

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procedures. PPM/ICD box means permanent pacemaker or cardioverter-defibrillator.

Page 6 Para 14

Magnet is in the small built in generator which will be used to recharge the depleted battery.

Page 6 Para 15

Objection has been incorporated in the new claims.

Page 6 Para 16 & 17

PPM/ICD box means permanent pacemaker or cardioverter-defibrillator.

Page 6 Para 18

Any soft material which will let the needle through and allow it to be insulated with the help of insulating sheath.

Page 6 Para 19

In technology being used for more than last 10 years the follow up of patients is done in following way.

There is a computer which is like various personal computers that we use in our households and can establish a stable internet connection. A telemetry wand kept on the patient skin establishes a connection between the PPM/ICD and the computer. The computer has software which helps in interrogating and checking various function of PPM/ICD and making some changes as desired. Cardiologist call it non invasive (patient skin has not been breached), engineers call it remote (PPM/ICD box not touched). Using this telemetry wand and computer, the cardiologist himself or with the help of PPM/ICD technician, carries out the PPM/ICD clinic.

I have suggested a system where this function can be done from distance that is that patient is not sitting in the PPM/ICD clinic and above function is done via internet thus it reduces cost of follow up and follow up is cheaply available round the clock. Only for some highly specific functions such as checking the defibrillation threshold, changing or upgrading software he has to visit the PPM/ICD clinic, which is an uncommon scenario.

Page 6 Para 20

Objection accepted and corrected in new claims.

Page 6 Para 21

Objection accepted and this particular claim has been deleted in new claims.

I will like you to note that all contents of new claims are there in specification submitted on August 19, 2003.

In claim 17 I have added following line after reading your references as I was not aware that there are so many other implantable medical devices which are based on pacemaker technology.

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"Wherein these changes can also be applied to other battery based implantable medical devices."

If you consider this addition objectionable please delete it.

*Claim rejections 33 US 193*

Page 6 Para 21

Instantly claimed application (10/642813): This application in contents is different from references cited in office action of April 24, 2006.

Page 6 & 8 Para 23- 28

Brownlee et al (4,134,408)

He uses the system of a transformer where electromagnetic induction is used. In transformer system two coils (primary and secondary) are used and depending upon the differential number of turns in coils decides voltage changes.

Brownlee et al (4,134,408): He describes above principle (claim 1 column 8, line 9-24).

Two coils primary (L1 of fig 1&2) for transmitting the electromagnetic induction, and secondary (L2 of fig 1 & 2) to receive it. There is no generator in his system.

Instantly claimed application (10/642,813): It uses a built in generator. In this a transformer system is not being used.

Brownlee et al (4,134,408)

For large coil patient furniture as bed and arm chair will be used in any plane (column 2, line 16-20)

Instantly claimed application (10/642813):

Well defined alignment. Note as it is using a different system from Brownlee et al (4,134,408).

Brownlee et al (4,134,408)

It describes a RF energy transmission and receiving system fig 3A 36, 38, 40 and 42 :  
See column 6 lines 21-32.

Instantly claimed application (10/642813): No such system as it uses a built in generator.

Munshi et al (5,411,537)

He has described the same system of electromagnetic induction (transformer) (column 10 lines 13-45) with two coils, primary is coil 72 and secondary is coil 74. This is similar to that described by Brownlee et al (4,134,408). Please note similarity of,

Fig 2 (Munshi) two coils 72 and 74 across skin,

Fig 1 & 2 (Brownlee) two coils L1 and L2 across skin.

Instantly claimed application (10/642,813): No such system as it uses a built in generator.

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Ogden (6,070,103)

He describes needle electrodes from one pole (fig 4), two poles (fig 8) and three poles (fig 11) to recharge the battery and change or upgrade the software of PPM/ICD.

The concept of insulated needles is not new to cardiology practice. I have personally used insulated needle for transcutaneous and transthoracic emergency temporary cardiac pacing in 1985, 1986, these became out of use with advent of external temporary pacing.

Instantly claimed application (10/642813):

I have described a needle system to connect the radiologically distinct pole.

I tested on some leather from the market which resembled human skin in thickness. In insertion the insulation gets damaged. Therefore initially a thick needle is used to create a small hole here. A fine needle is inserted which goes through the insulation up to the pole for recharging. The above step is confirmed by the fluoroscopy that the needle has reached the exact spot. An insulation is gently pushed on the needle. This insulation has thick terminal end and it compresses the PVC and gel like insulation on the pole on the PPM/ICD box.

Note this system of needle is different from Ogden (6,070,103).

Ogden (6,070,103)

He describes an implantable receptacle for receiving the above needle. This receptacle can be unipolar and of various shapes (fig 2A, 2C, 2D), bipolar (fig 7), tripolar (fig 10).

This can be on the PPM/ICD box or distantly placed (fig 4).

This receptacle chamber has many loose fibers (fig 2B, 16).

Instantly claimed application (10/642,813):

No such complex structure receptacle.

In this there are two radiological distinct poles. These poles can be localized on skin using the fluoroscopy of cath lab.

Note that in obese or female patient due to subcutaneous fat, it is not sometimes possible to localize the edges of box thus you need to know the exact location of the point where the needle will be inserted on the skin.

As an interventional cardiologist of more than twenty years of experience I can not understand how Ogden system receptacle will be localized inside the human body.

He has not described it.

Ogden (6,070,103)

Complex receptacle is used to change or upgrade software of PPM/ICD.

Instantly claimed application (10/642813):

Two simple radiological distinct poles to charge the battery only.

Ogden (6,070,103)

Single needle and unipolar receptacle and battery charged by grounding electrode 75 and box of PPM/ICD (fig 5)

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Application Dated August 19, 2001  
Reply to office action of April 24, 2002.

Instantly claimed application (10/642813).

Two simple radiological distinct poles as unipolar system can be dangerous if patient is pacemaker dependent and is using the box as an electrode in unipolar pacing mode.

Alt et al (5,725,559)

Describes a function where the software of PPM/ICD can be changed or upgraded non invasively.

Instantly claimed application (10/642813):

It only aims for follow-up from a centre which is located at a far distance from patient.

What Alt et al (5,725,559) describes is actually a complex function. For such complex function change or reassessing the change in defibrillation thresholds etc patient should physically be present in a dedicated clinic.

Page 9 Para 29

The box of PPM/ICD has several radiological markers. Some are outlined below

Marker to see that pacemaker lead pole is properly engaged in receptacle of PPM/ICD box.

Some companies such as CPI used to give radiological model no of PPM/ICD. Since we are not using these boxes now, I am not sure if CPI is still doing it.

I have added radiologically distinct pole, which is not difficult to do on the box of PPM/ICD.

Page 9 Para 30

As outlined above in drawing section when I tested the concept, above mentioned coils were used and they worked. I am not sure if other shape coils will work.

Page 9 Para 31

Fluoroscope facility (using X ray to see desired parts).

The cardiac cath lab where these procedures are carried are done on a U arm or C arm cath lab which provides multiplane moving arms to guide us with the therapy.

Page 9 Para 32

Software is preferably stored on non-rewritable CD so that it is not corrupted.

Page 9 Para 33

Brownlee et al (4,134,408), Munshi et al (5,411,537), Ogden (6,070,103), Alt et al (5,725,559)

Here the remote programming means that with the telemetry wand and computer the programming and the follow-up is done without making any incision over the body, and physically touching the PPM/ICD box. Thus here remote also implies non invasive as the PPM/ICD is not being physically handled but the patient is sitting or lying in dedicated PPM/ICD clinic.

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Instantly claimed application (10/642813)  
Here patient is not physically sitting in PPM/ICD clinic but with an internet connection he is connected to a remote (may be hundreds of miles away) PPM/ICD clinic.

Page 9 Para 34

Munshi et al (5,411,537)

He has described the same system of electromagnetic induction (transformer) (column 10 lines 13-45) with two coils, primary is coil 72 and secondary is coil 74.

Fig 2 (Munshi) two coils 72 and 74 across skin,

Instantly claimed application (10/642813): No such system as it uses a built in generator.

Munshi et al (5,411,537)

Describes plurality of current level functions, (claim 2)

Various chemical battery electrodes (claim 13, 14, 18, 19, 22, 30, 34,)

Various chemical structure for battery (claims 15, 20, 21, 23, 26, 27, 30, and 31)

Instantly claimed application(10/642813) :

No such changes.

Only common things in Munshi et al (5,411,537) and instantly claimed application (10/642813) are system for recharging battery and remote programming.

The differences in above are outlined above briefly again

Recharging battery

Munshi et al (5,411,537): uses a transformer system

Instantly claimed application (10/642813): uses a small built in generator

Remote programming

Munshi et al (5,411,537): non invasive and patient sits in dedicated PPM/ICD clinic.

Instantly claimed application (10/642813): patient may be hundreds of miles away from the dedicated PPM/ICD clinic.

### Conclusions

Page 9 Para 35

You are absolutely correct in your assessment that I am not familiar with patent prosecution procedure. I am an interventional cardiologist and I can not afford a patent attorney.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted

Vipul Narain Roy

(Dr. Vipul Narain Roy)

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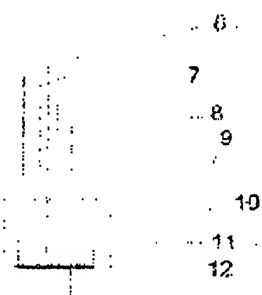


Figure 2



Application no. B-01-2001  
Application dated August 12, 2001  
Reply to office action April 24, 2006  
Annotated sheet showing changes

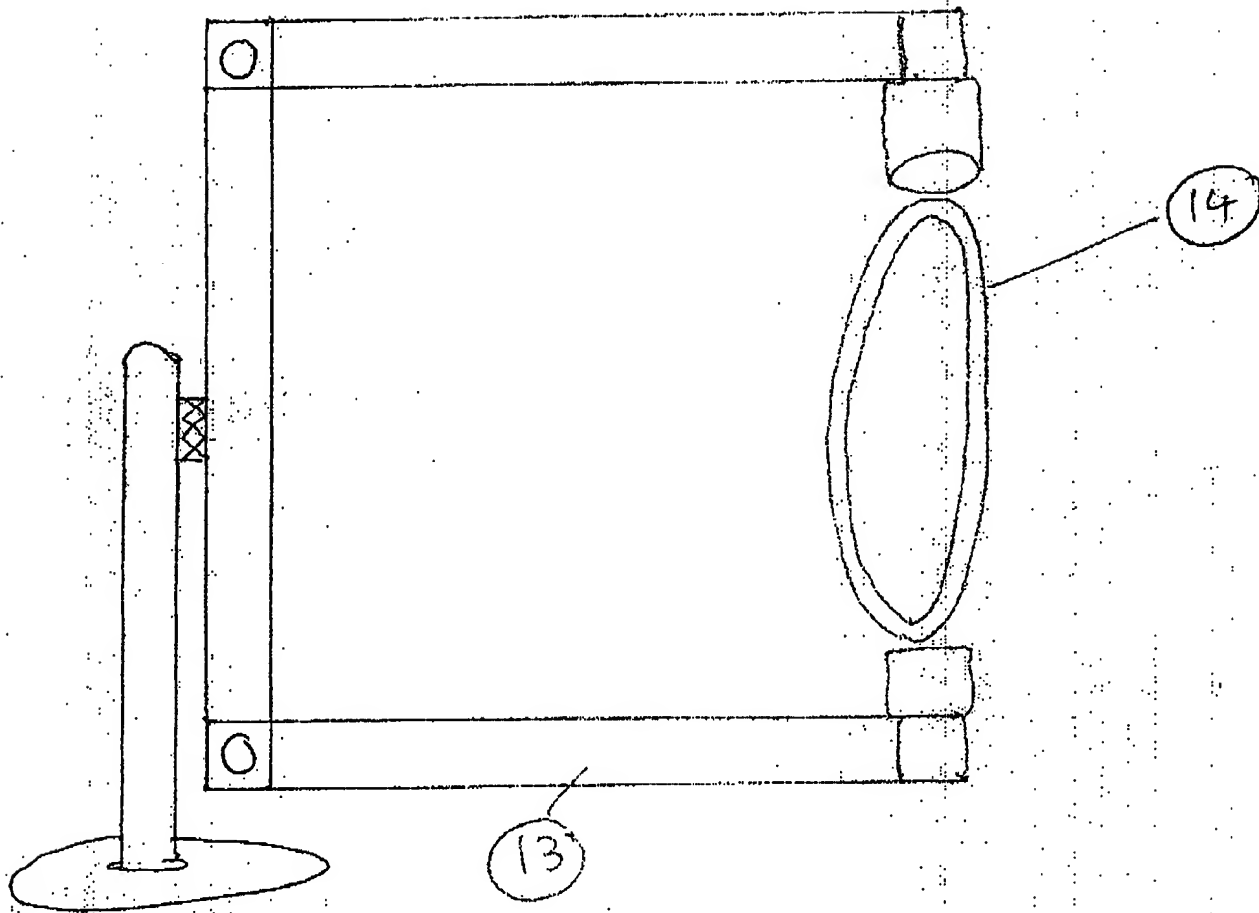


Figure 3.A  
(a)  
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